Products For Medicine, Inc.

XL 200 LED
Features, Specification, and Operation Instructions

Fiber Optic LED Light Source

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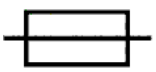
Table of Symbols

	CE Mark		Alternating Current
	Warning refer to user manual		Type BF
	Off		Intensity
	ON		Refer to user documentation
	ETL Mark		Catalog Number
	Fuse		Serial Number

	WEEE mark		Manufactured by

General Information and Warnings

Caution: Federal law restricts this device to sale by or on the order of a physician.
The PFM light source has been engineered with safety as a priority. However, the user is cautioned to observe the following:

1. Read and follow all instructions in this manual.
2. Never look directly at the light port when the unit is on; your eyesight may be compromised.
3. Take care removing fiber optic components or handling the light source; some surfaces may be hot.
4. Do not use this unit near water or in an area with excessive moisture.
5. Do not operate the unit without a fiber optic cable inserted in the port, the unit is powerful enough to burn skin if within contact of the opening.
6. Do not place flammable materials near the unit.
7. Do not defeat the safety purpose of the 3-prong grounded plug. Use only the approved power cord supplied with the unit. Route cord so it will not be pinched, severed or walked upon.
8. Do not defeat the purpose of the fuse. Replace only with the fuse type described in the manual and as marked on the unit.
9. Do not remove the cover. High voltage is present internally.
10. Keep all safety and operating instructions for future reference.
11. Do not block ventilation openings on this unit. Do not impede airflow.
12. If you wish to clean the unit, disconnect the power and use only standard detergent type cleaners; do not use solvents or petroleum distillates. Never “spill” liquid on the unit. Allow the unit to cool before cleaning.
13. Do not service the unit beyond what is described in this manual. Attempting repair of electronic or logic circuits without prior written approval of PFM will void the warranty. Should the light source fail at any time, return it to an authorized PFM service center.
14. For a Return Material Authorization, contact the PFM Customer Service department @ 800-333-3087

Product Description

The PFM light source family was designed to be backward compatible with previous PFM fiber optic accessories. Furthermore, with the proper adapter, the light source can accept all major brands of fiber optic component.

Please note: The XL 200 LED uses a unique adapter configuration. Use only PFM supplied adapters.

Installation Guidelines

To insure proper operation of the light source, the following conditions must be met:

Minimum Clearance

Rear	Sides and Top
1.5" (37 mm)	.5" (12.5 mm)

1. Do not block any air vents.
2. Proper ventilation must be provided at all times. Failure to do so may cause intermittent operation and/or failure of the electronics.
3. Avoid areas of excessive vibration.
4. Operate the light source only in an environment where people do not require protective equipment.
5. **CAUTION:** Dust accumulation will restrict air flow which can damage the unit. **(See Cleaning Section for recommendations)**

Indications for Use

The XL 200 LED light source is intended to provide white light to an accessory fiber optic light guide to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), and for use with a surgical headlight for general surgical or examination procedures.

Use with other equipment

Any equipment connected to the XL 200 LED light source must be certified to IEC60601-1 or other IEC/ISO standards appropriate to the equipment and application.

The user must not compromise the performance and safety requirements of the XL 200 LED light source when used with or near other equipment. The light source shall not be immediately adjacent to, beneath or above other electrical equipment.

All medical electrical equipment generates and receives electromagnetic and radio frequency interference (RFI) from other equipment. Use of the XL 200 LED near other equipment may adversely affect the function the light source or other equipment. It is the user's responsibility to verify using the XL 200 LED with or near other equipment will not adversely affect the performance of either unit.

Use of portable or other Radio Frequency (RF) telecommunications equipment may affect the performance of the XL 200 LED light source.

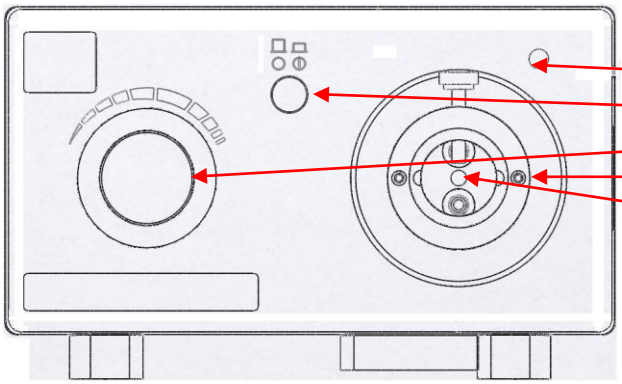
Do not touch any interconnections between electrical components and the patient at the same time. These include connections for video, data, control or power.

Use only PFM supplied components and/or cables with the XL 200 LED light source. Use of other components and/or cables may adversely affect electrical emissions or immunity.

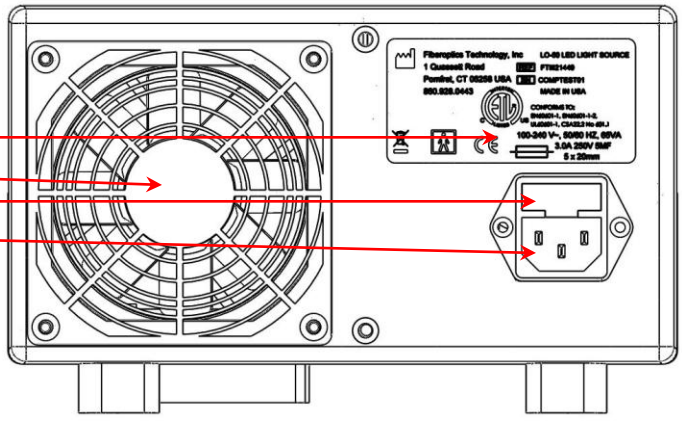
Operation

The XL 200 LED light source can be used around the world, operating with line voltages in the range 100 to 240 V AC and 50 or 60 cycle operation.

1. Make sure the power switch (2) on the front panel is in the "off" position.
2. Plug the power cord into the power connector (D) in the rear of the light source.
3. Plug the other end into a power source.
4. Inspect the optical element (5) to verify the element is clean. Clean per maintenance instructions if necessary.
5. Insert the appropriate adapter into bezel, aligning the through-hole in the adapter with the thumbscrew in the top of the bezel. Tighten the screw to capture the adapter, but not too far as to obstruct the opening for the fiber optic component.
6. Insert the selected fiber optic component.
7. Make sure the captive thumbscrew on the bezel goes through the adapter and locks the input of the fiber optic component in place.
8. Depress the power switch (2) to the "ON" position.
9. Adjust the light intensity with the intensity control knob (3) to desired setting.
10. To turn the unit off, press the power switch to the off position.



1. High temperature indicator
2. Power Switch
3. Intensity control
4. Bezel (Accepts adapter not shown)
5. Optical Element



A. Power rating
B. Fan
C. Fuse
D. Power connector

Intensity regulation

The intensity control must be turned to the 9 o'clock position before you will notice any output. This is normal, and does not affect performance.

Lamp Intensity

Just like halogen lamps, LEDs, degrade over their lifetime, most by an average of 15%. However, the difference between the two types is lifetime. Instead of degrading 15% over 200 hrs, LED will degrade 15% over 50,000 hours, with the change of intensity over time barely noticeable.

Furthermore, LED arrays are not created equal. As proven by independent research, LED arrays, like their Halogen counterpart, may vary +/- 20% in maximum intensity, depending on the batch.

Additionally, color temperature can vary from unit to unit. This is considered normal, and is the result of the manufacturing process for LED "chips".

PFM LEDS are bin selected for color temperature and power, and should not vary by more than 5%

Finally, heat plays a critical role in LED power and life. Make sure all vents are free from obstruction. Make sure the fan is running, and the unit is not in a restrictive enclosure. If the LED gets too hot, you could experience a dramatic decline in output, and the unit's temperature monitor may disrupt power to the lamp.

Maintenance

LED Replacement

These chip arrays should last, on average, 50000 hr. If a chip requires replacement, contact the factory for service.

Fuse Replacement

Under normal use, the fuse should not require replacement. The purpose of the fuse is to protect the electronics from failure due to inrush. Should it become necessary to change the fuse, replace with the same type (2amp/quick blow) to insure long life and best performance.

Cleaning

The housing has a durable finish that should retain its original luster for many years. Cleaning the exposed areas with a commercial glass cleaner or common household detergent will help maintain the finish.

Unplug and remove the power cord from the IEC connector on the back of the unit. Wipe the exposed areas of the housing with a soft cloth or paper towel moistened with general purpose cleaner.

CAUTION: Do not use excess water, treated cloth, harsh cleaning agents or sprays. Use cleaning fluid sparingly. If fluid spills into the interior, let the unit dry thoroughly before using.

Periodically, dust should be removed from the unit using a vacuum. Pay special attention to the air vents at the rear of the unit, in the front (around the bezel), and on the bottom of the main housing.

The optical element in the front light port should be inspected before use to verify there is no contamination. If contaminated, clean with soft cloth, or swab, and alcohol. Allow alcohol to dry completely before using light source.

Use of Filters
There is no filter drawer or filter receptacle on the XL 200 LED.

Troubleshooting
If you are unsuccessful at resolving the following conditions, contact PFM for a Return Material Authorization (RMA). Do not attempt to repair the light source. Tampering with the electronics will void the warranty.

Fan operates, but unit has low light output.

- Insure the fiber optic component is clean, undamaged, and fully seated.
- Check the intensity setting.
- Make sure there are no obstructions blocking the cooling vents.
- Verify optical element in light port is clear
- Verify light guide is correct size. The output size of the light source is 5.0mm. Smaller diameter light guides will work, but will have lower light output.

Fan operates, but output is intermittent (every few minutes, unit turns off and turns on).

- The light source is running too hot. A thermal cutoff protects the circuitry from heat damage.
- Possible Causes
    - Inadequate Air Flow
        - Check air intakes and exhaust areas for dust or dirt accumulation.
        - Make sure minimum clearances are maintained. (See installation guidelines for clearance information).
        - Move the light source to a cooler ventilated location. NEVER enclose the light source without adequate ventilation.
    - Fan failure
        - Fan will be visible through rear vent. Verify fan is rotating.
        - If fan is not rotating, return unit to manufacturer for servicing.

Fan operates, light is not on.

- The chip may have failed. Contact the factory.

Fan does not operate, light is on.

- Return unit to manufacturer for servicing.

Fan and light are not working.

- Make sure the power cord is inserted completely into the IEC connector and also into the power source.
- Check the power cord for damage.
- Check the fuse.
- Check the outlet.

Fiber input is burning.

- Check the fiber type…it may be plastic and susceptible to burning. All standard PFM fiber optic light guides are made with glass fibers.
- Contamination on fiber.
    - Verify fiber face is clean.
- Contamination on light source optical element
    - Verify optical element is clean.
- Light guide is damaged.
    - Replace light guide. PFM offers a repair service and replacement light guides. Contact PFM for more information.

Ask your light guide supplier about the epoxy used to manufacture the fiber optic input…some epoxy types cannot withstand the high photonic energy developed by this light source.

Product Specifications

Improvements may result in specification or feature changes without notice.

Physical Dimensions

Overall Height:	5.0" (121 mm)
Overall Width:	7.625" (205 mm)
Overall Depth:	7.75” (219 mm)
Unit Weight:	13.5lbs. (4.8 kg) including cord
Adapter Receptacle:	1” (25.4mm) OD.
Adapter:	5 different types: Storz, ACMI, Wolf, Olympus, Pilling
Power Requirements:	100-240 VAC, 50/60Hz
Power Consumption:	65 Watts (65VA)
Fuse:	2A Type F Quick Blow
Classification:	Type BF, Class II
Electrical Safety:	IEC/EN 60601-1:2006 UL 60601-1:2003 CSA C22.2 No. 601.1 1990 (R2005)
Electromagnetic Compatibility:	IEC 60601-1-2:2007

Recommended Conditions

- Operating
  - Temperature 5°C to 40°C
  - Humidity 10% to 85% Relative Humidity, Non-Condensing
- Storage
  - Temperature 5°C to 50°C
  - Humidity 10% to 85% Relative Humidity, Non-Condensing

Customer Support

PFM maintains support services to assist you. Please contact your representative for support. You may also contact us directly by phone, facsimile, mail or e-mail at:

PFM Customer Service Department
1201 E. BALL RD # H
ANAHEIM, CA. 92805 USA
800-333-3087 toll-free within US and Canada
+001 714 991 8222
Monday - Friday 8AM - 4PM PST USA
WWW.PRODUCTSFORMEDICINE.COM

Be sure to have your part number and serial number available, as well as a complete description of the problem or situation for the quickest, most accurate assistance.

Service/RMA Policy

There are no user serviceable parts in this product. Service required for any reason must be performed by PFM or an authorized service representative. All service outside warranty will be performed with purchaser's approval, and charged according to normal service charges in effect at the time.

To return any item, whether for warranty repair or chargeable servicing, an RMA number (Return Material Authorization) must be obtained from PFM. This number must be clearly visible on the shipping label. All shipping must be prepaid.

If the light source was used in a biohazard environment, you may also be asked to supply a certification stipulating the conditions of service, including a list of materials the light source may have been exposed to. This unit must be clean and decontaminated before shipment. PFM reserves the right to return any product contaminated with blood or other organic material without repair.

PFM guarantees all warranty repairs will be completed within two weeks of receipt. All units will ship prepaid using our shipping method of choice. Alternate shipping methods will be shipped freight collect.

Warranty

PFM warrants its family of light sources to be free from defects in material and workmanship for a period of two years from date of shipment unless stated otherwise in a specific separate published warranty.

If any PFM product is found to have defects in material or workmanship the purchaser should notify PFM promptly, and request an RMA number. After an RMA number is assigned, purchaser may return defective products prepaid to the originating PFM facility.

PFM, at its sole discretion, will repair or replace PFM products found to be defective, and return said products, prepaid. PFM's correction of any defects, by the grant of credit, repair, or replacement, shall constitute fulfillment of all obligations and liability to the purchaser hereunder.

PFM is not responsible for damage to product caused by abuse or neglect, unauthorized installation, maintenance, use, repair, or adjustment. Any of the aforementioned actions shall make this warranty null and void and shall relieve PFM from any further responsibility hereunder.

PFM shall not be liable for any incidental, special, or consequential damages in any claim action, suit or preceding arising under this warranty or any other part of the agreement of sale between PFM and the purchaser, nor shall there be any liability hereunder for labor claims, loss of profits or good will, repairs or other expenses incidental to replacement.

The foregoing warranty is in lieu of all other representations and warranties expressed or implied, written or oral, including warranties of merchantability or fitness of the goods for a particular purpose, unless exception is offered in writing by an officer of PFM, or separate published warranty is cited for specific product groups.

The warranty is void if:

- We determine the product has been subjected to neglect or misuse or has been installed following procedures not in accordance with our instruction manual.
- Unauthorized repairs or modifications have occurred.
- The warranty seal has been broken or the serial number label has been altered.

Our obligation is limited to repair or replacement, FOB ANAHEIM, CA. We will not be held responsible for consequential damages, transportation, installation, adjustment or other expenses arising in connection with our products or parts.

This warranty is in lieu of all other statements or guaranties, written or implied by PFM or our authorized representatives.

Liability

Any warranty implied under State Law shall be limited to one year from original delivery to original purchaser. Specifically excluded from PFM liability is damage resulting from acts of any deity, malicious mischief, vandalism, riots, wars, improper installation or neglect in the operation or maintenance of the unit or misunderstanding of the properties of the unit. Under no circumstances shall PFM be obligated for consequential or other damages of any kind or description, losses or expenses in connection with or by reason of the use of, or inability to use this unit for any reason. The stated warranty provides the purchaser with specific legal rights, and there may be additional rights which vary from State to State. Some states, for example, do not allow exclusion of consequential damage.

Table 1 - **Guidance and Manufacturer's Declaration – Electromagnetic Emissions**

The XL 200 LED Light Source is intended for use in the electromagnetic environment specified below. The user of the XL 200 LED Light Source should ensure that the device is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Group 1	The XL 200 LED Light Source uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The XL 200 LED Light Source is suitable for use in all establishments, including domestic establishments and those directly connected to public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Essential Performance

The XL 200 LED Light Source is safe and effective when used in the electromagnetic environment specified in Tables 2 through 4.

Table 2 - **Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

The XL 200 LED Light Source is intended for use in the electromagnetic environment specified below. The user of the XL 200 LED Light Source should ensure that the device is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC-61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The XL 200 LED Light Source is suitable for use in a dry environment.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the XL 200 LED light source requires continued operation during power mains interruption, the light source should be powered from an uninterruptable power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the mains voltage before application of the test level.			

Table 3 - **Guidance and Manufacturer's Declaration – Electromagnetic Immunity**

The XL 200 LED Light Source is intended for use in the electromagnetic environment specified below. The user of the XL 200 LED Light Source should ensure that the device is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to the XL 200 LED light source than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	$d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Note 1: At 80MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by adsorption and reflection from structures, objects and people.			

a. While medical equipment is normally compliant with IEC 60601-1-2 emission required, field strength from fixed transmitters such as cell phone towers, or terrestrial radio and TV transmitters cannot be predicted. Therefore, an electromagnetic site survey should be considered to verify compliance with the electromagnetic environment required above. If the measured environment exceeds that recommended, the user should monitor the XL 200 LED for abnormal performance.
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Table 4 – **Recommended Separation Distances between Portable and Mobile RF Communication Equipment and the XL 200 LED light source**

The XL 200 LED light source is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the XL 200 LED light source can help prevent interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the XL 200 LED light source as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	**80MHz to 800 MHz** $d=1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d=1.2\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter., where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by adsorption and reflection from structures, objects and people.

DECLARATION OF CONFORMITY

WE, PRODUCTS FOR MEDICINE

DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE FOLLOWING PRODUCT NUMBERS LISTED;

XL 200 LED LED LIGHT SOURCE.

TO WHICH THIS DECLARATION RELATES, ARE IN CONFORMITY WITH THE DIRECTIVE AND STANDARDS LISTED BELOW.

MEDICAL DEVICE DIRECTIVE 93/42/EEC.
IEC 60601-1
UL 60601-1
CSA C22.2 NO. 601.1
IEC 60601-1-2

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